Study Type and Performance Site Information

Type of study:

[ ] Standard or Expedited
[**x**] **Exempt**
[ ] Umbrella Review for funds release
[ ] Comparative Effectiveness Research
[ ] Non-Human Subject Determination
[ ] Quality Improvement/Non-Research Determination
[ ] Request review by another IRB
[ ] Coordinating Center ONLY

Please indicate which Committee is most appropriate to review your project:

[ ] Social and Behavioral Sciences
[**x**] **Health Sciences**

Are there any international sites involved in this study in which the PI is responsible?

[ ] Yes
[**x**] **No**

Is this project cancer-related?

[ ] Yes
[**x**] **No**

Study Purpose and Description

Provide a brief abstract of the study in lay language. The IRB Committees are comprised of scientists with varied backgrounds, non-scientists, and community members.

Adverse events - harm to patients that results from medical care - are common and difficult to identify and measure using existing tools. Accurate real-time measures of adverse events would enable organizations to track harm over time, identify and prioritize areas for safety improvements, evaluate whether patient safety programs are effective, and communicate risks of harm to patients and caregivers. Through SPEEDe, we will develop an innovative machine learning approach for accurately detecting adverse events in the elderly in real-time.

[Please note: SPEEDe is a larger project . This particular protocol focuses only on the planned secondary use / chart review activity of SPEEDe. We separated the secondary use out for this exempt protocol, and are pursuing a separate IRB application for the other aspects of the study. These other aspects, e.g. the usability study, Delphi, interviews, etc. are not covered by this exempt protocol, and are still under development. We have attached the entire grant proposal for the IRB's reference.]

Does your study fit into one or more of the listed categories of exemption (45 CFR 46.104)?

[ ] (d)(1) Research involving normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction such as: (1) Most research on regular and special education instructional strategies; or (2) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management.
[ ] (d)(2) Research that only includes interaction involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following is met: (1) Information obtained is recorded by the investigator in such a manner that the identity of human subjects cannot be readily ascertained; or (2) Any disclosure of the human subjects' responses outside of the research would not reasonably place the subjects at risk or; (3) The information obtained is recorded by the investigator in a manner that could identify the human subjects directly or through identifiers linked to the subjects.
[ ] (d)(3): Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collected and at least one of the following is met; (1) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained; (2) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk; or (3) The information obtained is recorded in a manner that could identify the human subjects directly or through identifiers linked to the subjects. Note: Children may not be included in research under this exemption.
[**x**] **(d)(4): Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria are met: (1) The identifiable private information or biospecimens are publically available; or (2) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, the investigator does not contact the subjects, and the investigator will not re-identify subjects; or (3) The research involves only information, collection, and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA for the purposes of "health care operations" or "research", or for "public health activities and purposes" under HIPAA; or (4) The research is conducted by, or on behalf of a Federal department or agency using government-generated or government-collected information obtained for non-research activities.**
[ ] (d)(5) Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study public benefit or service programs for federally supported projects and most appropriately invoked with authorization by the funding agency, procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or possible changes in methods or levels of payment for benefits or services under those programs.
[ ] (d)(6) or 21 CFR 56.104(d) Taste and food quality evaluation.
[ ] No category fits what I want to do.

Describe the source of data/specimens and if these are publicly available. If not publicly available, describe how prior approval will be obtained before accessing this information (attach approval letter if available).

We will use data collected through chart review, the Clarity data warehouse and the Research Derivative (RD). All identified data will be reviewed, then recorded as deidentified data with study IDs only. The proposed project does not plan to re-identify any deidentified records using the identified VUMC database.

The Research Derivative is a database of clinical and related data derived from the Vanderbilt University Medical Center's (VUMC) clinical systems and restructured for research. Data is repurposed from VUMC's enterprise data warehouse, which includes data from StarPanel, VPIMS, and ORMIS (Operating Room Management Information System), EPIC, Medipac, and HEO among others. The medical record number and other person identifiers are preserved within the database. Data types include reimbursement codes, clinical notes and documentation, nursing records, medication data, laboratory data, encounter and visit data, among others. Output may include structured data points, such as ICD 9 or 10 codes and encounter dates, semi-structured data such as laboratory tests and results, or unstructured data such as physician progress reports. The database is maintained by the Office of Research Informatics under the direction of Paul Harris, Ph.D.

Will you be recording or keeping any of the 18 HIPAA identifiers?

[**x**] **Yes**
[ ] No

Indicate how appropriate protections are incorporated to ensure the privacy of subjects and confidentiality of data:

Data will be kept on password-protected Vanderbilt computers and only available to study staff. No PHI will be released to any parties outside of study staff, and all reported data will be deidentified and in summary form.

Please indicate what existing materials you are collecting:

[**x**] **data from the medical record or clinical record**
[ ] specimens
[ ] data from the synthetic derivative
[ ] specimens from BioVU
[ ] other materials

Recruitment

Will the study provide compensation to research participants?

[ ] Yes
[**x**] **No**

PHI/Consent

Are you requesting a waiver of authorization to use/record protected health information?

[**x**] **Yes**
[ ] No

Please describe the plan to protect the identifiers from improper use and disclosure.

All data will be stored on password-protected Vanderbilt computers, and only accessible to the small group of study staff who are all trained in safekeeping PHI. No data will be reported except in summarized, de-identified form in peer reviewed journals and presentations.

Please describe how the privacy risks to individuals whose protected health/private information is to be used are reasonable in relation to the anticipated benefits (if any) and the importance of the knowledge expected from the research.

No data will be reported except in summarized, de-identified form in peer reviewed journals and presentations. Insights from this study will be used to identify causes of adverse events and approaches for preventing them, with the goal of improving safety for hospitalized adults.

Please indicate the source of the PHI to be collected.

The retrospective data for this study will be collected from Clarity, the clinical data warehouse and the Research Derivative (RD).

Please indicate when PHI will no longer be accessed.

PHI will no longer be accessed once the study has concluded.

Please explain why the research could not practicably be conducted without accessing/using the protected health information:

It would not be feasible to conduct chart reviews without accessing the PHI.

Please describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

PHI will be destroyed once the study has concluded.

Please verify that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research.

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Does this research disclose Protected Health Information (PHI)?

[ ] Yes
[**x**] **No**

Conflict of Interest Disclosure

Is there a potential conflict of interest for the Principal Investigator or key personnel? • The PI is responsible for assuring that no arrangement has been entered into where the value of the ownership interests will be affected by the outcome of the research and no arrangement has been entered into where the amount of compensation will be affected by the outcome of the research. • Assessment should include anyone listed as Principal Investigator, or other research personnel on page 1 of this application. Please note that ownership described below apply to the aggregate ownership of an individual investigator, his/her spouse, domestic partner and dependent children). Do not consider the combined ownership of all investigators.

[ ] Yes
[**x**] **No**